App. No. 10/522,887
Office Action Dated January 26, 2009

REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. The specification has been amended to address formal issues. Claims 17 and 23-4 have been amended. The amendment to claim 17 is supported for example by pages 8-9 of the specification. The amendment to claim 23 is supported for example by page 9 of the specification. Claim 24 has been amended editorially. Claims 29-33 are new, and are supported for example by page 9 of the specification. No new matter has been added. Claims 17-20, 23-25 and 29-33 are pending.

Claim rejections - 35 U.S.C. § 112

Claims 23 and 24 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Claims 23 and 24 have been amended, taking the issues noted in the rejection into account.

Withdrawal of the rejection is respectfully requested.

Claim 24 is rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. To satisfy the deposit requirement, the Examiner is requiring a statement that the specific strains will be available to the public under the conditions specified in 37 CFR 1.808-1.809. A declaration by the Applicant satisfying the deposit requirements under 37 CFR §§ 1.803-1.808 will be submitted. Applicants respectfully request withdrawal of the enablement rejection once the declaration has been submitted.

Claims 23 and 24 are rejected under 35 USC 112, second paragraph, as being indefinite. Claims 23 and 24 have been amended, taking the issues noted in the rejection into account.

Withdrawal of the rejection is respectfully requested.

Claim rejections - 35 U.S.C. § 103

Claims 17-20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Plant Science, 148: 131-139, 1999) in view of Bowler et al. (European Patent Publication No. EP 0359617A2), Nayak et al. (Proc. Natl. Acd. Sci, 94(6):2111-6); Verdaguer et al. (Plant Mol. Biol., 31(6):1129-39) and Davuluri et al. (Meeting Abstract, Plant Biology, 1999: 103). Applicants respectfully traverse the rejection.

The rejection recognizes that Tanaka et al. do not teach the transformation of indica rice, or a MnSOD encoding sequence derived from *Nicotiana Plumbaginifolia L.*, or a Pea ribulose-1-

5-bisphosphate carboxylase small subunit transit peptide coding sequence, or a CVMV promoter, but contends that it would have been obvious to combine Nayak et al., Bowler et al., and Verdaguer et al., and Davuluri et al. and produce the transgenic plant of claim 17 with a reasonable expectation of success. Applicants respectfully submit that the references do not provide any reasonable basis to conclude that a stable transformation of indica with *N. Plumbaginifolia L.* MnSOD as recited in claim 17 can be achieved.

In particular, Nayak teaches in the second column on page 2115 that past efforts of transformed plants with unmodified incesticidal crystal protein (ICP) genes were proven unsuccessful due to some mechanism that operates between transcription initiation and mRNA degradation. To address such issues, Nayak indicates that significant modifications to the ICP genes were necessary to prevent mRNA decay. Such results clearly substantiate the general understanding in the art of plant transformation that unintended molecular effects can be expected when crop plants are genetically transformed with genes from other species. Factors that are responsible for such unpredictability include, for example, differences in the transgene integration site and locus configuration. Insertions of foreign genes can cause mutations, or harbor small or large DNA sequence rearrangements at the right or left border junction sites, including target site deletions, duplications, translocations and insertions of filler sequences representing the vector backbone or host sequences. Thus, significant variation can be expected where the host genomes are different, especially if the plants are from or related to different species.

It has been well established that indica and japonica can be clearly distinguished based on physiological and morphological traits including drought tolerance, potassium chlorate resistance, phenol reaction, plant height and leaf color. In fact, biochemical and molecular studies have shown that indica and japonica strains are closer in some characters or loci to different *O. rufipogon* strains than they are to each other (Hirano et al., J. Mol. Evol. 38:132-137 (1994)), indicating that indica and japonica are descended from ancestors of two different species. In particular, studies of the two genomes have shown that japonica strains are closely related to the perennial strains of one group, and the indica strains are closely related to another species, *O. rufipogon*, which is an annual strain (Chang et al., Mol. Biol. Evol. 20(1):67-75(2003)).

Given such differences, there is no reasonable basis from Tanaka to conclude that Tanaka's studies using a different transgene and host genome would lead to a predictable application in Nayak's indica rice variety. As noted previously, Tanaka indicates that stable transformation of crop plants using the SOD is unpredictable, especially if different genomes are used (page 136). Nayak's experiments substantiate the general understanding that there are multiple sources of unintended changes in transgenic plants, including the transgene itself. Tanaka, Nayak, Bowler and Verdaguer in fact all use different transgenes and host genomes with varying degree of success in obtaining stable transformations.

Moreover, the frequency of rearrangements varies significantly when using different transformation techniques. For example, particle bombardment is a potent technique for integration, but generally causes substantial disruptions of plant DNA and rarely gives rise to simple integration patterns. Nayak utilizes particle bombardment to transform indica rice with an ICP gene. Verdaguer also utilizes the particle bombardment to transform japonica with CVMV promoters, but utilizes electroporation to introduce *A. tumefaciens* into *N. tabacum*. Tanaka utilizes electroporation to transform Sasanishiki with yeast mitochondrial MnSOD. Bowler utilizes *A. tumefaciens* treatment to transform *N. plumbaginifolia* with *N. plumbaginifolia* MnSOD. Davuluri is silent as to which crop plant was transformed. Thus, the references evoke important questions as to which transformation technique would cause the lowest number of disruptions for the indica host genome with *N. Plumbaginifolia L.* MnSOD to give stable transformations. Applicants submit that the teachings in the references substantiate the general understanding in the art of plant transformation that application of transformation protocols which minimize variability among transgenic plants is complicated and remains unpredictable by widely occurring species or variety specificity with respect to transformation procedures.

As is clear from the above discussion, Tanaka, Bowler, Nayak, Verdaguer and Davuluri do not provide any reasonable basis to lead one to expect with any reasonable degree of certainty that stable transformation of the indica rice can be achieved with *N. plumbaginifolia* MnSOD. Accordingly, claim 17 and the dependent claims therefrom are patentable over Bowler and Tanaka for at least these reasons.

New dependent claims 29-32 and independent claim 33 are further removed from the references.

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Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Dated: July 27, 2009

Respectfully submitted,

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